Food and Drug Administration
OFFICE OF CRIMINAL INVESTIGATIONS
MEMORANDUM OF INTERVIEW

CASE NUMBER:	2016-MWM-709-0576-J
CASE TITLE:	THERANOS, INC.
DOCUMENT NUMBER:	287628
PERSON INTERVIEWED:	Sarah Bennett
PLACE OF INTERVIEW:	Webex
DATE OF INTERVIEW:	12/11/2020
TIME OF INTERVIEW:	1:00 PM EST
INTERVIEWED BY:	ASAIC George Scavdis
OTHER PERSONS PRESENT:	See below.

On December 11, 2020, the case agent interviewed Sarah Bennett, Technical Lead, Division of Clinical Laboratory Improvement and Quality, Centers for Medicare and Medicaid Services (CMS), regarding a survey she conducted of Theranos in September and November of 2015. The interview was conducted via Webex. Also present were Assistant United States Attorney (AUSA) Robert Leach, United States Attorney's Office for the Northern District of California, and Lindsay Turner, attorney, CMS Division, Health and Human Services, Office of General Counsel.

Ms. Bennett earned a Bachelor of Science in medical technology in 1981 from a medical college in the State of Virginia. She worked in private laboratories from 1981 through 2007, mostly in hospital laboratories and in physicians' offices. In some of those laboratories she was a supervisor. She worked for the State of Maryland in 2007, during which time she conducted surveys. In 2011, Ms. Bennett began working for CMS, where she also has conducted surveys. Within CMS, she is a subject matter expert (SME) in the following Certified Laboratory Improvement Amendments (CLIA) areas: Personnel requirements for enforcement for competency assessment; proficiency testing (PT); PT referral; individual quality control (QC) plans; and surveyor training. In 2018, she became a technical director within the CLIA program. She has been involved in writing regulations and policy and in performing surveys. All told from 2007 to the present, Ms. Bennett has probably conducted between 30 and 40 laboratory surveys.

Ms. Bennett explained what it means to be consider an SME for personnel. If there is a question in interpreting the personnel regulations, within CLIA she is considered a person to go to when the regulations need to be interpreted. She is the lead for State Agency Enforcement Review (SAER) and for principles of documentation. She is certified from the Society of Clinical Pathology.

Ms. Bennett explained that PT referral is if a laboratory takes a PT sample that they are supposed to be testing themselves and instead sends it to another laboratory. Labs must do PT for those tests that they offer to patients.

Ms. Bennett explained what individual QC plans are. The CLIA regulations allow for QC to be performed as it's outlined in the regulations; however, if there is information about an alternate QC plan in the state guidelines in which the laboratory is situated, a laboratory can use those to develop a QC program. QC is a process that laboratories use to ensure that their test results are accurate and reliable at the time they were run. There are several types of QC. Procedural QC makes sure the system is working correctly. This is

usually implicated at point of care testing where they do the testing at the patient's bed side and results are available right away. Internal QC (usually in the same types of point of care testing) is about checking to make sure that the system is working correctly. It sometimes takes the place of external controls. Internal QC makes sure the system is measuring the values the machine gives correctly. The external control is usually a liquid that mimics what a human specimen would. A laboratory would run the control the same as it would a patient sample, from beginning to end. For tests where you're trying to get a result that is a normal value, the QC control sample must be in an acceptable limit for the laboratory to report patient results.

Ms. Bennett explained that PT is a set of unknown samples that a lab receives from a PT program three times a year. The laboratory tests them and sends the samples back to the program. The program grades the laboratory's responses to the samples and informs the laboratory if they passed or failed.

Elizabeth Holmes and several people from Theranos came to CMS to discuss the Theranos business model. Theranos requested to come in and present their business model to CMS, and a meeting was held in person. Ms. Holmes was at that meeting, as well as Judy Yost from CMS. Ms. Bennett can't recall who else was there. Theranos presented some materials at the meeting. Ms. Holmes presented the Theranos business model and explained that they wanted to put their "black box" into pharmacies, and that people would go in and get their blood drawn. An electronic signal would go to California where the results would be read. CMS told Ms. Holmes all those pharmacies would need a CLIA certification. Ms. Holmes said Theranos was working with the FDA. Theranos debated the need for the pharmacies to have their own CLIA certification. Ms. Bennett doesn't recall who exactly from Theranos pushed back on that. Ms. Bennett had no understanding at this time that Theranos had a CLIA certification. She had no idea what tests or devices Theranos was using in their laboratory. She believes Theranos presented a Phase I and a Phase II plan, and Phase I entailed putting the "boxes" in the pharmacies. CMS told Theranos they needed to go to the FDA first, and Theranos said they were already in talks with the FDA. CMS said FDA would have to categorize their tests as waived tests for Theranos to get a certificate of waiver.

Ms. Bennett explained there are four types of CLIA certificates. These certifications exist to make sure labs provide accurate, timely and reliable results; these minimal requirements are set to ensure that. As the testing gets harder, the requirements become more stringent. The four types of certificates are certificates of waiver, certificates of microscopy, certificates of compliance, and certificates of accreditation. A certificate of waiver means a laboratory may only perform those tests categorized by FDA as waived. Those tests are easy to perform, and an erroneous result would have a negligible effect on patient's health. A certificate for microscopy covers a laboratory test looking for microscopic particles in urine, etc. Those labs can also perform waived tests. A certificate of compliance means a lab can perform any test from waived to high complexity. A certificate of compliance imposes personnel requirements, facility requirements, requirements related to quality of testing, and PT requirements. Finally, a certificate of accreditation allows for the same type of testing as certificate of compliance. The difference is, this is overseen through an accreditation organization, instead of the state, like with certificate of compliance.

The meeting between CMS and Theranos occurred in Baltimore, Maryland. The next time Ms. Bennett encountered Theranos was during her September 2015 survey of them. CMS had received complaints about Theranos at the same time Theranos was due for their recertification survey, so they combined the complaint survey and the recertification survey into one. The complaints were received by Gary Yamamoto at CMS's San Francisco Regional Office, but he sent them to Ms. Bennett in advance of the survey. One complaint was from Erika Cheung. Ms. Bennett doesn't recall the name of the other complainant.

Ms. Bennett gets involved in surveys at CMS, and she's been asked to do federal jurisdictional surveys. Because of her history of being a surveyor with the State of Maryland, she was asked to help with federal jurisdictional surveys. Federal jurisdictional surveys cover those laboratories that are directly overseen by the federal government. There have been other times when the CMS regional office has specifically requested that she participate as part of a survey team. With Theranos her boss, Karen Dyer, asked her to participate. Ms. Bennett was asked to participate because of her survey experience and because of the nature of the complaints--leadership made the decision it would be good to have someone from Baltimore involved. Ms. Bennett said the complaints implicated PT, QC, and inaccurate testing.

Ms. Bennett and Mr. Yamamoto had several calls prior to the Theranos survey to go over their process and approach. They pulled up Theranos's PT history and their previous survey report to make sure they corrected previously identified issues. They talked about logistics and the complaints. At the time of the survey, Ms. Bennett had not contact with any reporters. She doesn't believe she knew that a Wall Street Journal reporter was asking questions about Theranos. The survey was set up by CMS's San Francisco office.

Ms. Bennett said there was a lot of security at Theranos during her survey. She and Mr. Yamamoto were escorted to a room and were not allowed to go anywhere without an escort. Ms. Bennett was put in a room and told to wait for an interview for a very long period. She had asked to interview one of the staff members, and they insisted that legal counsel be there for the confidential interview. Ms. Bennett said no and then waited for a long time. The employee came in and said she would speak to Ms. Bennett but would only speak with counsel present. After every question Ms. Bennett asked, the employee looked at Heather King before she would answer. Ms. Bennett never had an experience like this in a confidential interview; normally counsel is not present during the survey. She had never been in a laboratory with the level of security she saw at Theranos.

Ms. Bennett said Theranos's laboratory looked very much like any other clinical laboratory you would see. It was no different than any large clinical laboratory she had seen. Ms. Bennett explained that in a survey the first thing she does is have an entrance conference where she explains why they are there. This happened during the survey of Theranos. Then they took her and Mr. Yamamoto on a tour of the lab. Most of the time there was always a Theranos attorney in the conference room with them. Ms. Bennett and Mr. Yamamoto came back after the tour and explained what kind of documents they wanted to see. As issues came up, they would ask to go to the laboratory, and they would be escorted to where they needed to go. Ms. Bennett recalls engaging with the QA/QC manager, Langley Gee. Sunny Balwani was there, as well as various technical supervisors. Doctor Young from Phoenix was also there along with several technical staff. There was always at least one attorney present with Ms. Bennett and Mr. Yamamoto. When Ms. Bennett and Mr. Yamamoto would ask for documents, someone from Theranos would leave and it would be several hours before they came back. When they came back, they would give them the wrong document. When CMS came back in November, they told Theranos "We're not doing this again" regarding waiting long periods of time for documents.

Mr. Balwani engaged mostly with Mr. Yamamoto. Ms. Bennett described Mr. Balwani as someone who did not defer to many people. Mr. Balwani talked a lot in the September meeting. Ms. Bennett described the categories of documents that they asked Theranos for: PT documents; documents related to testing; and QC documents. Pretty much everything they asked for Theranos had trouble providing. Ms. Bennett said, "To be frank, it was very challenging." It was challenging for CMS because it was hard to decide about compliance when they couldn't get the documents they needed. This was unusual in her experience.

CMS always asks for a current test list, which Theranos provided. Initially, Theranos did not provide the proprietary testing information because they said they were no longer using those tests. As a result, Theranos thought they didn't have to provide it. Ms. Bennett pushed back and said she needed to know what tests they were running on the proprietary test system and the start and stop dates. She asked for it because CMS knew the device had been used since the last inspection. Ms. Bennett asked for the start and stop dates for the proprietary device and that is what Mr. Balwani gave her the next day. She needed that information to investigate the complaint, which was about the proprietary device. Ms. Bennett reiterated that initially they asked for a list of all the tests and a list of the devices those tests are being run on. She also asked for the list of the tests Theranos ran on the proprietary test. Mr. Balwani responded that they were no longer using the device. She said she needed it anyway, and he said he would get it for her the next day. Ms. Bennett said, "That's it." Ms. Bennett doesn't think Ms. Holmes was at the September survey, but she was Ms. Bennett's "shadow" at the November survey. AUSA Leach showed Ms. Bennett a copy of a letter dated September 23, 2015, and Ms. Bennett identified it as the document Mr. Balwani produced to her in response to her request that Theranos provide the start and stop date of their proprietary testing. (Attachment one)

Ms. Bennett explained that a laboratory developed test (LDT) is a test that is developed by one laboratory and only used by that laboratory; it can't be marketed or sold. Her understanding at the time of the survey was that Theranos was not running any tests on their proprietary device.

Ms. Bennett's understanding when she went into the Theranos laboratory for a tour was that they were using FDA approved or cleared devices. She noted that Theranos was modifying the devices and that she and Mr. Yamamoto found out about that during the survey. Her understanding was there were no proprietary devices being used by Theranos when she was there in September 2015. She explained that cleared and approved are two different processes; one is a 510(k) process and one is an PMA (pre-market approval). During the survey, Ms. Bennett was in the venipuncture lab, and Mr. Yamamoto was in the fingerstick lab. The fingerstick lab had a Tecan machine which would dilute the samples so that they could be put on the analyzer. In the fingerstick lab, they were diluting the samples to run on the FDA cleared devices. Ms. Bennet looked at Prothrombin Time during the survey and Theranos had major issues there.

Ms. Bennett explained that modifying FDA devices is not a problem under CLIA, the laboratory just must do extra work. Instead of verifying the manufacturer's instructions, they have to start from ground zero and show how the test is accurate and precise. They must ESTABLISH performance specifications instead of VERIFY them. In her experience, modification doesn't happen that often, or the lab doesn't realize they've modified a test by, say, picking a different sample type than what was cleared by FDA. In the package insert, the manufacturer puts in what precision studies show, what accuracy studies show, and what's the lowest setting they can pick up, etc.

Ms. Bennett explained that if a laboratory is developing an LDT or modifying an FDA cleared device, the laboratory must establish analytic sensitivity and analytic specificity. Analytic sensitivity refers to being able to detect the lowest amount of whatever a laboratory is looking for. For example, if a laboratory is measuring glucose and the manufacturer says you can report out glucose between 40 and 400, but you modify it and say you will report down to 20, the laboratory has to show it can get an accurate result from between 20 and 40. Analytic specificity refers to how well the method measures what a laboratory is looking for. Continuing the glucose analogy, analytic specificity would measure if the test is picking up just glucose, or if it is picking up other sugars.

Ms. Bennett didn't get any additional information during the survey on why Theranos stopped doing those tests on their proprietary platform. She doesn't recall Theranos saying who made that decision. She said Mr. Gee was extremely difficult and that he deflected every question she asked him. Overall, her experience at the survey was extremely challenging and frustrating. Ms. Bennett and Mr. Yamamoto came out a second time in November 2015 because they didn't get to finish in September 2015. Part of that was because it was so difficult to get information, and the change of the fiscal year accounted for the lag time.

For both the September and the November survey, Theranos requested a conference at the end of each day for CMS to go through their findings. There was always debate, and Mr. Balwani was the one doing the debating in September. Regarding the November survey, it was very much the same with the security presence. Theranos attorneys were always present and Ms. Holmes was there by either the first or second day. Mr. Balwani stayed with Mr. Yamamoto during the survey and Ms. Holmes stayed with Ms. Bennett. Ms. Bennett and Mr. Yamamoto told Theranos that if they didn't get documents to them in a reasonable amount of time, they would assume Theranos didn't have them. They had discovered the issue in September with Theranos's Prothrombin Time (the coagulation test) tests, and Theranos had not notified any of the affected patients until they day before CMS showed back up to Theranos in November. The results of the coagulations tests are very important. Clinical decisions were made based upon those results. The regulations required that as soon as Theranos became aware of an erroneous patient test result, they had to notify the patient, and in the case of the affected coagulation tests it took them seven weeks to do so. She asked them why it took so long and there was really no response. She can't recall who at Theranos she asked. She had talked to them about the Prothrombin Time findings at the end of the day during the September survey.

Ms. Bennet explained the CMS finding under CLIA of "Immediate Jeopardy." She described it as a situation where the laboratory must take immediate action to correct the underlying issue because the patient could die or be adversely affected--there is a likelihood it could cause injury or serious harm to a patient or death. It refers to the potential for something to be a risk to human health. When CMS left in November, they explained to Theranos that they were considering a finding of Immediate Jeopardy. CMS told Theranos they were definitely out of compliance at the Condition Level and that they were considering Immediate Jeopardy. On the last day of the November survey, Ms. Holmes tried to get CMS to reconsider their citations. Ms. Holmes seemed to be upset and concerned about what CMS would write in the Statement of Deficiencies (CMS 2567), and she appeared to want CMS to not cite what they were going to cite. Ms. Holmes was emotional. Mr. Balwani was there for this meeting.

Everywhere Ms. Bennett went in November, Ms. Holmes went. When Ms. Bennett would find something, Ms. Holmes would want to debate about it. Ms. Holmes was trying to spin it to get Ms. Bennett to consider that what she was seeing wasn't actually a deficiency. At one point in November, Ms. Holmes had to get someone to swipe them in to a portion of the lab. Ms. Holmes seemed to be very knowledgeable about what was where. Ms. Bennett isn't sure how much technical information she knew.

AUSA Leach showed Ms. Bennett the January 25, 2016, letter from CMS to Theranos attaching the CMS 2567. (Attachment two is too large to load electronically into AIMS) Dr. Sunil Dhawan was at the survey but he didn't interact with Ms. Bennett or Mr. Yamamoto; he sat quietly and didn't say a word. He was there for only a short period of time. Ms. Bennett can't speak to how common it is for CMS to find Condition Level deficiencies on a survey. The CMS 2567 is the official record of the survey. The CMS 2567 for Theranos's survey was drafted by Ms. Bennett and Mr. Yamamoto. Drafting the CMS 2567 is part of her responsibility when she conducts a survey.

Ms. Bennett explained that each regulation has a deficiency tag (ID prefix tag), and it's just a numerical code that matches up with a regulation. She explained that on page one of the CMS 2567, 493.84 (e) Routine Chemistry is the regulatory citation, and the description contained under it is the actual regulation. The information the surveyor manually puts in can be found after the sentence that begins "Based on…" The findings support the deficient practice statement. The "3rd event" referenced on page one refers to the 3rd PT event of 2014. Ms. Bennett explained that individuals aren't identified in CMS 2567s, their titles are used instead.

Ms. Bennett explained that on page two, 493.851(e) Hematology, it states that in the 2nd event of 2014, when Theranos turned in their PT results and got them back, they gave the wrong answer on a blood cell identification, but they did not investigate why it was wrong.

Ms. Bennett said CLIA has a requirement that a laboratory must enroll in and participate for PT for regulated analytes for their primary testing method. The laboratory determines what their primary method is. CMS can only go by what the lab says as to what their primary testing method is. Laboratories are graded by instrument and reagent. CMS doesn't really have the ability to guess what a laboratory's primary device is--they must go by what's on the laboratory's PT form. The complaint CMS received regarding Theranos was that they were doing testing on the Edison as their primary device but were submitting PT for testing done on another device. CMS didn't have the ability to question that. It did appear that Theranos was submitting PT testing for samples run on non-Edison devices, however. Theranos was also failing to meet the regulatory requirement to investigate unsatisfactory results.

AUSA Leach directed Ms. Bennett to page three of the CMS 2567, 493.1215 Hematology. She explained that in the CLIA regulations, there are Standard Level and Condition Level deficiencies. Being out at the Condition Level is much more serious than being out at the Standard Level. Hematology is a specialty within CLIA that covers white blood cell count (WBC), red blood cell count (RBC), anemia, looking at the cells within the blood, and coagulation (PT/INR). Ms. Bennett can only speak to the findings that she wrote on the CMS 2567. The issues she found were related to the PT/INR coagulation testing and it had to do with Theranos using expired reagents and QC not being acceptable, yet Theranos still reporting out patient results. A laboratory must determine for each level of QC what the acceptable values are going to be before they release patient results.

If the QC results are not within their acceptable range, the laboratory should not be reporting out patient results. Theranos was sending out patient results without passing QC.

Ms. Bennett said there was a big problem with PT/INR that she discovered during the survey. Theranos used expired reagent and hadn't done the study for the reagents. QC was unacceptable and they released test results. Their freezers and refrigerators were at different ranges than the manufacturer recommended, and Theranos didn't notice it. Theranos was releasing inaccurate results and clinicians were making decisions based on those results. Ms. Bennett said patients on coagulation therapy need accurate results. Refrigerators could have affected stability of the reagents. If they don't investigate problems of PT/INR, it could keep a systemic error hidden and it would be impossible to know if patients were affected. Theranos had quality assessment (QA) issues regarding making sure all their lab operations were operating as they should be. Basically, QA is an audit of the laboratory's process, and Theranos was not doing it the way their procedures said they should.

Ms. Bennett said Theranos had "major issues" with the Edison device. She said their laboratory had a procedure on how they would validate those tests, and they didn't follow their own procedure. So, there was no way to know if they met the accuracy needed for testing. Additionally, they were reporting patient results out when QC was not acceptable on the devices. She was told by Theranos during the survey that when QC was unacceptable, the device locked you out for 24 hours; she found out that wasn't true. Theranos was required to compare all the Edison devices, and they were not doing that completely. If they're not following their procedures and their acceptability criteria, there is no way to know the accuracy and reliability of their results.

With the Edison, Theranos wasn't following their own validation procedures. For establishing performance specifications, one would expect to see all the steps in their procedure. When Theranos set out the steps as to how to determine whether the test was accurate or precise, they did not follow what was in their procedure. If the QC results were bad on one device, they'd just move testing to another device, and then go back to the bad device the next day without any investigation as to why the device did not pass QC the day before. Ms. Bennett said if that's the process, the laboratory can't tell if the underlying tests are accurate and reliable. During her survey, she sampled data; she did not review data from all of them. She didn't have time to do all the devices, so she picked three or four systems to look at. She found the same issues across the tests that she looked at.

AUSA Leach directed Ms. Bennett to page eight of the CMS 2567, 493.1250 Analytic Systems. Ms. Bennett explained the testing process is broken up into pre-analytic, analytic, and post-analytic. Pre-analytic is when the laboratory is getting the specimen ready, and the laboratory is either accepting or rejecting the specimen. Analytic is the actual testing of the specimen. Post-analytic is when the laboratory reports out the final result. In the case of Theranos, this was a Condition Level deficiency. Ms. Bennett worked on a portion of this part of the survey. She looked at the procedures not signed and dated by the lab director, and she looked at the issues related to ID deficiency tags D5421 and D5423. Regarding D5421, that refers to the fact that the manufacturer, not the laboratory, performed the verification studies, and CLIA requires that the laboratory perform them. Regarding chemistry, Theranos did not perform certain chemistry tests they were required to perform.

All these CLIA requirements are a means to make sure patient results are accurate and reliable. What Ms. Bennett can say about the survey is that Theranos didn't meet the regulatory requirements. Any time that a lab is non-compliant with a deficiency, there is the potential that lab test results could be affected.

Theranos was cited for using expired reagent. Their procedure said they always had to look at package inserts for new lots of reagent. Ms. Bennett examined a reagent package insert that was pink (they are normally white) and it clearly said the reagent shelf life was much shorter than normal. Theranos didn't even notice it until she pointed it out to them, and they used it for some months. It's not the manufacturer's responsibility to notice the change, it is the laboratory's.

AUSA Leach directed Ms. Bennett to page nine of the CMS 2567. Prior to May 15, 2014, Theranos didn't

have a procedure for QC for the Edison device, and if you go back to the letter that Mr. Balwani gave Ms. Bennett, it stated that Theranos was performing patient testing on the Edison with no QC procedure to tell them what was acceptable and what was not. Either that or they could not produce a document during the survey showing that they were performing QC prior to that time. Ms. Bennett explained that a laboratory must know what the acceptability is for QC in order to know if their test results are accurate and reliable.

AUSA Leach directed Ms. Bennett to page 12 of the CMS 2567, specifically to the text discussing CL SOP 09161. Mr. Dhawan had left by this time. Ms. Bennett explained that there are lab director responsibilities imposed by CLIA, and the signing and dating of procedures is not one of the lab director's responsibilities that can be delegated to someone else. The lab director must do it and it must be done before the laboratory uses the procedure. Theranos was using a procedure that was not signed, dated and approved by a lab director. The lab director is responsible for the overall operation of the lab and that's why it's a problem. The procedure tells the laboratory personnel how they are expected to run testing.

AUSA Leach directed Ms. Bennett to page 18 of the CMS 2567 to the portion beginning with Calcium. Here, the manufacturer performed the verification studies when CLIA requires the laboratory to do it. Theranos didn't do any verification on the plasma samples they were running, and the manufacturer did their verification studies on serum, not plasma. The manufacturer's accuracy study only went down to 4.58, and Theranos was reporting out results outside of that range. Ms. Bennett explained that "precision" is how well a laboratory can reproduce the same answer. A laboratory must make sure there is precision in the instrument and precision across operations. Theranos only did run precision, they didn't do day to day, run to run, or operator to operator precision. What Theranos did was "incomplete."

AUSA Leach directed Ms. Bennett to page 37 of the CMS 2567, D5481 – Edison daily QC procedures. The general supervisor told Ms. Bennett that if the QC was unacceptable on an Edison device, the device locked out the operator for 24 hours. If the QC was bad on a given device, Theranos would just move to another device. They would then go back to the failed device 24 hours later, and if the QC was good that day, they'd run patient results without doing an investigation. She found that patient results were run on devices that were supposed to have been locked for 24 hours due to failed QC inside of that 24 hour lock out period. Ms. Bennett and Ms. Yamamoto were finding the issues across multiple assays.

AUSA Leach directed Ms. Bennett to page 41 of the CMS 2567, subpart "s." Her review found that Theranos had 113 days where their QC was at least plus or minus two standard deviations above or below the acceptable level established for QC.

AUSA Leach directed Ms. Bennett to page 47 of the CMS 2567, D5791. QA is a process that a laboratory uses to audit their laboratory operations. They define what they're going to look at, and at what intervals. Theranos was not following their own QA procedure. They did not know there was a problem until Ms. Bennett pointed it out to them, yet their QA/QC manager was signing off that they were every month. Subpart "b" is telling the reader what Ms. Bennet looked at during the survey. Referring to subpart "c," Theranos's procedure said they required the CV (coefficient of variation) to be a certain amount, but when she reviewed the documentation for Vitamin B12 for this device, it showed that the CV was higher than that. That does not meet their criteria for acceptability, and they did not react to that. There was no reaction, and no action to correct. They simply signed off on it and moved on. It's a problem because it shows there is a large range of controls that are not meeting their acceptability requirements, so they should not be reporting out patient results. It should have been a red flag that there was a problem with those devices, and they should have investigated the issue. Ms. Bennett believes she asked for QC, and they gave her reports that had the device numbers on them. She explained, say for instance you had a glucose of 100--if you had a 40% CV, you're saying it's okay if the real result is anywhere from 60 to 140; that is clinically significant.

Ms. Bennett said, "There is a systemic issue of quality. Across the board, not just with the Edison but also their other testing."

Ms. Bennett said the CMS 2567 reflects what CMS found to be the deficient practices on the survey. That is all it is. CMS had no preconceived notions going into the Theranos survey at all. Even if they had had

knowledge of newspaper articles in advance, it wouldn't have changed their mission during the survey.

SUBMITTED: Electronically submitted by GEORGESCAVDIS

GEORGE SCAVDIS, ACTING SPECIAL AGENT IN CHARGE DATE: 12/17/2020

APPROVED: Electronically approved by MARKMCCORMACK

MARK MCCORMACK, SPECIAL AGENT IN CHARGE DATE: 12/17/2020

DISTRIBUTION: Orig: MWM w/attachments
cc: Prosecution w/attachments

ATTACHMENTS: 1 - September 23, 2015, letter given to CMS by Sunny Balwani
2 - Statement of Deficiencies (CMS 2567)

theranos

1701 Page Mill Road
Palo Alto, CA 94304
P 650.838.9292
F 650.838.9165
theranos.com

CONFIDENTIAL COMMERCIAL INFORMATION
EXEMPT FROM DISCLOSURE UNDER THE FREEDOM OF INFORMATION ACT

September 23, 2015

To Whom It May Concern:

You requested a current list of the platforms on which all of our tests are running as of September 22, 2015. We are providing that information to you under separate cover. Additionally, the following is the list of the Laboratory Developed Tests (LDTs) that Theranos tested on Theranos device, also called Theranos Sample Processing Units (TSPUs), along with the time periods when those tests were run. Theranos recently received FDA clearance for its Theranos System – including the device, the Theranos Sample Collection Device (including the nanotainers) and other components of the system - , and plans to bring these units live again in the lab as 510k-cleared analyzers, rather than LDTs, once additional clearances are obtained.

As we explained in person, Theranos changes the platforms on which it runs tests from time to time. The decision to move testing off of TSPUs and onto other platforms in this case was a business decision to transition to the manufacturing quality systems to QSR compliance under FDA guidelines and does not reflect on the reliability or accuracy of any platform.

Theranos has never commercially distributed a TSPU.

Test	Initial	End
Vit D	11/6/2013	3/10/2015
TSH	11/7/2013	2/4/2015
FT4	11/11/2013	2/4/2015
TPSA	11/11/2013	6/25/2015
TT3	2/12/2014	2/4/2015
TT4	2/12/2014	2/4/2015
TST	3/19/2014	3/10/2015
HCG	5/9/2014	1/19/2015
SHBG	7/28/2014	6/25/2015
VB12	8/12/2014	3/6/2015
Estradiol	9/25/2014	12/18/2014
Prolactin	9/25/2014	12/18/2014